Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in this application.

1. (Original) Crystalline *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride.

2. (Original) The compound of Claim 1 which is characterized by an x-ray powder diffraction pattern having two or more diffraction peaks at 2θ values selected from the group consisting of 15.61±0.2, 16.32±0.2, 19.50±0.2, 24.25±0.2, 24.92±0.2, 25.45±0.2, 28.67±0.2, and 31.16±0.2.

3. (Original) The compound of Claim 1 wherein the x-ray powder diffraction pattern comprises diffraction peaks at 2θ values of 24.25±0.2, 24.92±0.2, and 25.45±0.2.

4. (Original) The compound of Claim 1 which is characterized by an x-ray powder diffraction pattern in which the peak positions are substantially in accordance with the peak positions of the pattern shown in FIG. 1.

5. (Original) The compound of Claim 1 having an infrared absorption spectrum with significant absorption bands at 696±1, 752±1, 787±1, 827±1, 873±1, 970±1, 986±1, 1020±1, 1055±1, 1066±1, 1101±1, 1197±1, 1293±1, 1371±1, 1440±1, 1542±1, 1597±1, 1658±1, 2952±1, 3372±1, and 3555±1 cm^{-1}.

6. (Original) The compound of Claim 1 which is characterized by a differential scanning calorimetry trace which shows an onset of endothermic heat flow at about 200°C.

7. (Original) A hydrochloride salt of *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-

hydroxyphenyl)ethylamine having an x-ray powder diffraction pattern having two or more diffraction peaks at 2θ values selected from the group consisting of 15.61±0.2, 16.32±0.2, 19.50±0.2, 24.25±0.2, 24.92±0.2, 25.45±0.2, 28.67±0.2, and 31.16±0.2.

8. (Original) A pharmaceutical composition comprising a therapeutically effective amount of the compound of Claim 1 and a pharmaceutically acceptable carrier.

9. (Original) The pharmaceutical composition of Claim 8, wherein the composition comprises particles of crystalline *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride having a size ranging from about 1 μm to about 10 μm.

10. (Original) The pharmaceutical composition of Claim 8, wherein the composition further comprises a therapeutically effective amount of one or more other therapeutic agents.

11. (Original) The pharmaceutical composition of Claim 8, wherein the composition is formulated for administration by inhalation.

Claims 12-14 (Canceled)

15. (Withdrawn) A process for preparing crystalline *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride, the process comprising the steps of:

(a) dissolving *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine in a first polar solvent to form a first solution; and

(b) adding hydrochloric acid to form a second solution from which a crystalline product is formed.

16. (Withdrawn) The process of Claim 15 wherein the second solution comprises isopropanol and water in a ratio of isopropanol:water of from about 4:1 to about 10:1, volume to volume.

17. (Withdrawn) The process of Claim 15 further comprising:

(a) dissolving the product of Claim 15 in a second polar solvent; and

(b) adding between about 0.5 and about 1.5 equivalents of hydrochloric acid per mole of free base and a third polar solvent to form a third solution from which a crystalline product is formed.

Claims 18 and 19 (Canceled)

20. (Original) A pharmaceutical composition comprising:

(a) *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride;

(b) a buffering agent; and

(c) water;

wherein the buffering agent is present in an amount sufficient to provide the composition with a pH in the range of between about 4 and about 6.

21. (Original) The pharmaceutical composition of Claim 20 wherein the buffering agent is present in an amount sufficient to provide the composition with a pH in the range of between about 5 and about 5.5.

22. (Original) The pharmaceutical composition of Claim 20 where the buffering agent comprises a citrate species.

23. (Original) The pharmaceutical composition of Claim 20 wherein the composition is isotonic.

24. (Original) The pharmaceutical composition of Claim 23 wherein the composition further comprises a sufficient amount of sodium chloride to render the composition isotonic.

25. (Original) The pharmaceutical composition of Claim 20, wherein the composition further comprises a surfactant.

26. (Original) The pharmaceutical composition of Claim 20, wherein the composition further comprises a therapeutically effective amount of one or more other therapeutic agents.

27. (Canceled)

28. (Withdrawn) A process for preparing a pharmaceutical composition for use in a nebulizer, the process comprising the steps of:

(a) dissolving crystalline *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride in an acidic aqueous solution comprising a buffering agent; and

(b) adding a base until the composition has a pH of between about 4 and about 6.

29. (Withdrawn) The process of Claim 28 wherein the acidic aqueous solution is an isotonic solution.

30. (Withdrawn) The process of Claim 28 wherein step (b) comprises adding NaOH until the composition has a pH in the range of between about 5 and about 5.5.

31. (Withdrawn) A method of treating a disease or condition in a mammal associated with β_2 adrenergic receptor activity, the method comprising administering to the mammal, a therapeutically effective amount of a pharmaceutical composition of Claim 8 or Claim 20.

32. (Withdrawn) The method of Claim 31 wherein the disease or condition is a pulmonary disease.

33. (Withdrawn) The method of Claim 32 wherein the pulmonary disease is asthma or chronic obstructive pulmonary disease.

34. (Withdrawn) The method of Claim 31 wherein the disease or condition is selected from the group consisting of pre-term labor, neurological disorders, cardiac disorders, and inflammation.

Claims 35 – 40 (Canceled)